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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,911	08/01/2000	JERRY KANELLOS	47-139	2571

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EXAMINER	
SNEDDEN, SHERIDAN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,911	KANELLOS ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 2 December. Claims 1-22 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn. Applicant's main premise is that Winkleman or Amrani do not teach the heparin precipitation of fibrinogen followed by the extraction of fibrinogen with 0.1 M or greater NaCl. Applicant has successfully argued that the use of the NaCl solutions in Winkleman or Amrani would not read upon the extraction step recited in the claims. Therefore, previous rejections relying on Winkleman or Amrani are withdrawn in favor of the following.

New Rejections

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 15-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkleman (US Patent 4,789,733), in view of Pines *et al.* (US 5,605,887).

Winkleman teaches the enrichment of fibrinogen and Factor VIII from blood plasma fraction, especially cryoprecipitate (see abstract; regarding claim 2, 15, 19, and 21). This was achieved by the addition of at least 0.15 mg/ml of sulphated polysaccharide, especially heparin

(regarding claim 7-9), to form a precipitate containing fibrinogen (see abstract; regarding claims 1 and 14, step (i)). In the paragraph bridging columns 5 and 6, Winkleman suggests that this precipitate containing fibrinogen may be further processed to extract fibrinogen. In example 24, a composition of FVII and fibrinogen is gel purified, lyophilized and heated for viral inactivation as preparation for pharmaceutical use (regarding claims 11-12 and 17-18).

Winkleman does not expressly teach a method for extracting fibrinogen from the heparin-precipitate. Additionally, Winkleman does not expressly teach the use of ε-aminocaproic acid (claim 6), the use of chromatographic techniques for the further purification of fibrinogen (claim 13), or the additional step of purifying fibrinogen away from fibronectin or Factor VIII (claim 14(iii)).

Pines *et al.* teach a fibrinogen extraction buffer comprising sodium chloride, 52.6 gm, for final concentration 150 mM (or about 0.2 M NaCl); sodium citrate, 88.23 gm, for final concentration 50 mM; dibasic sodium phosphate, 42.59 gm, for final concentration 50 mM; and epsilon-aminocaproic acid "EACA" 78.71 gm, for final concentration 100 mM. EACA is a tissue enzyme inhibitor, e.g. plasmin inhibitor, which would preserve the integrity of fibrinogen. This extraction buffer was applied to a precipitate containing fibrinogen made using PEG-1000 instead of heparin (see Example 1).

Taken together, the above reference teaches the method of obtaining fibrinogen consistent with the method steps and reagents of claims 1-22. It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the extraction buffer of Pines *et al.* to extract fibrinogen from the heparin-precipitate of Winkleman. The additional steps and/or reagents of the present invention are commonly used for the purposes of extracting

fibrinogen or for preparing pharmaceutical compositions. Thus, the current claims are directed to a method that would appear to be nothing more than the result of routine optimization using reagents known to the prior art, as noted "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). Routine optimization is not considered inventive and no evidence has been presented that the selection specific buffer concentrations was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

A person of ordinary skill in the art would have been motivated, and would have expected success, to combine the above steps and reagent as each step and reagents are well described in the prior art in methods of extraction and purification of fibrinogen. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

4. Claims 1, 13, 14 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkleman and Pines *et al.* as applied to claims 1, 2, 4, 5 and 22 above, and further in view of Altieri *et al.* Claims 13 and 14 add the additional step of purifying away fibronectin and Factor VII, as suggested by Winkleman at column 5 and 6 above. Altieri *et al.* teach how this additional step would be executed. Altieri *et al.* teach the use of a Sepharose.TM. 4B column (Pharmacia LKB, Piscataway, N.J.) to remove any possible contamination of the purified

fibrinogen with fibronectin, the purified fibrinogen preparation which resulted in fibronectin-free fibrinogen (regarding claims 13 and 14(iii)).

Thus, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use chromatography for the purposes of extracting fibronectin or Factor VIII from a fibrinogen enriched preparation. A person of ordinary skill in the art would hace expected success in furthering enriching fibrinogen by following the teaching of Altieri *et al.* Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

5. No Claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

SKS
April 5, 2004
SKS

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER